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#### UNITED STATES PATENT AND TRADEMARK OFFICE

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### BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte VLADIMIR GRUBAC, MATTHEW D. BONNER, RAYMOND W. USHER, THOMAS A. ANDERSON, and ARSHAD A. ALFOQAHA

Appeal 2014-009725 Application 13/096,881 Technology Center 3700

Before MICHELLE R. OSINSKI, PHILIP J. HOFFMANN, and TARA L. HUTCHINGS, *Administrative Patent Judges*.

OSINSKI, Administrative Patent Judge.

### DECISION ON APPEAL

### STATEMENT OF THE CASE

Vladimir Grubac et al. (Appellants)<sup>1</sup> appeal under 35 U.S.C. § 134(a) from the Examiner's decision rejecting claims 5, 7, 12–14, 19–30 and 39, which are all of the pending claims.<sup>2</sup> We have jurisdiction under 35 U.S.C. § 6(b). An oral hearing was held on March 23, 2017.

We REVERSE.

<sup>&</sup>lt;sup>1</sup> Appellants identify the real party in interest as Medtronic, Inc. Appeal Br. 2.

<sup>&</sup>lt;sup>2</sup> Claims 1–4, 6, 8–11, 15–18, and 31–38 are cancelled. *See* Amend & Resp. (Dec. 2, 2013).

### THE CLAIMED SUBJECT MATTER

Claims 5, 7, 12, 19, 20, and 39 are independent. Claim 5 is reproduced below and is illustrative of the claimed subject matter on appeal.

## 5. An assembly comprising:

an implantable medical device; and

a set of active fixation tines attached to the implantable medical device,

wherein the active fixation tines in the set are deployable from a spring-loaded position in which distal ends of the active fixation tines point away from the implantable medical device to a hooked position in which the active fixation tines bend back towards the implantable medical device,

wherein the active fixation tines are configured to secure the implantable medical device to a patient tissue when deployed while the distal ends of the active fixation tines are positioned adjacent to the patient tissue;

wherein the active fixation tines are configured to deploy from the springloaded position to the hooked position by releasing the active fixation tines in unison from the spring loaded position and allowing the active fixation tines to assume the hooked position;

wherein the active fixation tines are positioned substantially equidistant from each other in a circular arrangement; and

wherein the active fixation tines are configured to create opposing radial forces when deployed in unison such that the active fixation tines pull the implantable medical device towards the patient tissue when the active fixation tines are deployed while the distal ends of the active fixation tines are positioned adjacent to the patient tissue.

### **EVIDENCE**

The Examiner relied on the following evidence in rejecting the claims on appeal:

Hastings US 2007/0219590 A1 Sept. 20, 2007

## THE REJECTION<sup>3</sup>

Claims 5, 7, 12–14, 19–30 and 39 stand rejected under 35 U.S.C. § 102(b) as anticipated by Hastings. Final Act. 2–5.<sup>4</sup>

## **OPINION**

The Examiner finds that Hastings discloses all of the limitations of independent claims 5, 7, 12, 19, 20, and 39, including, *inter alia*, active fixation tines that "are deployable from a spring-loaded position in which the distal ends of the tines point away from the IMD [implantable medical device] to a hooked position in which the active fixation tines bend back towards the IMD." Final Act. 2, 4. The Examiner points to any embodiment of Figures 11C–D, 11E–K, or 11V–W. *Id.* at 8.

We first address the Examiner's position as it relates to the embodiment of Figures 11C–D of Hastings. As to the requirement that the active fixation tines "bend back towards the IMD," the Examiner takes the position that bending back towards the IMD reasonably encompasses "rotat[ion] or deform[ation] back towards the device." Final Act. 3. More particularly, the Examiner finds that Hastings's "tines [of the embodiment of Figures 11C–D] go from facing longitudinally forward the axis of the device to facing perpendicular the device after deployment . . . [and, thus,] have

<sup>&</sup>lt;sup>3</sup> The rejections, under 35 U.S.C. § 103(a), of claim 15 as unpatentable over Hastings and Herbert (US 2005/0209653 A1, pub. Sept. 22, 2005) (Final Act. 6), and claim 16 as unpatentable over Hastings (*id.* at 5–6) are moot in view of the cancellation of claims 15 and 16, and are not before us on appeal.

<sup>&</sup>lt;sup>4</sup> Although the Final Rejection lists claims 1–14, 17–30, and 39 under this rejection (Final Act. 2), the Answer clarifies that the rejection concerns only claims 5, 7, 12–14, 19–30 and 39, which are all of the pending claims (Ans. 3).

rotated or deformed back towards the device relative to the originally straight/parallel and forwardly-oriented projection." *Id.*; *see also* Ans. 3, 4–5 (the Examiner finding that the tines of Hastings' embodiment of Figures 11C–D are forced to "translat[e] 90 degrees relative to their original orientation in a direction that is clearly traversed back towards the device itself," so as to move from a "longitudinally-facing position to facing perpendicular to the device").

Appellants argue that the tines of the embodiment of Figures 11C–D of Hastings cannot be considered to "bend" merely because they rotate to point in a different direction. Appeal Br. 13; Reply Br. 5. Appellants maintain that "[r]otation or pivoting of a body is not bending it" (Appeal Br. 13) and "[i]f the tines are always straight, they do not bend" (Reply Br. 5).

During examination, claim terms are given their broadest reasonable interpretation consistent with the Specification. *In re Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1369 (Fed. Cir. 2004). Appellants' Specification consistently uses the term "bend" to describe what happens to the active fixation tines when changing from a first configuration in a spring loaded position to a second configuration in a "hooked" position. *See, e.g.*, Spec. ¶¶ 30, 39, 50, 51, 67. In other words, the term "bend" is used in connection with the changing of the distal ends of the active fixation tines from a first configuration in which each distal end has a relatively straight portion that points away from the implantable medical device to a second configuration in which each relatively straight portion of the distal end is curved into a hooked position. *See, e.g.*, bend. (n.d.) *Random House Kernerman Webster's College Dictionary*. (2010). Retrieved April 12, 2017 from http://www.thefreedictionary.com/bend (defining "bend" as "to force from a

straight form into a curved or angular one or from a curved or angular form into a different form"). We determine that the Examiner's interpretation of "bend" that would extend to mere rotation of the active fixation tines is not reasonable in the context of the Specification. Therefore, we determine that the Examiner erred in finding that the embodiment of Figures 11C–D of Hastings discloses "active fixation tines [that] are deployable from a spring-loaded position . . . to a hooked position in which the active fixation tines bend back towards the implantable medical device" (as set forth in each of independent claims 5, 7, 12, 19, 20, and 39) under the broadest reasonable interpretation standard.

We next address the Examiner's position as it relates to the embodiment of Figures 11E–K of Hastings. We determine whether the Examiner had a sound basis for finding that Hastings' adjustable tines 1110E are capable of meeting the functional language of the claims. *See In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (holding that before an applicant is required to provide that the subject matter shown to be in the prior art does not possess the characteristic relied on, the Examiner must provide sufficient evidence or scientific reasoning to establish that there is a sound basis for the Examiner's belief that the functional limitation is an inherent characteristic of the prior art). As to the functional language of the claims, the Examiner finds that the structure of Hastings "meets all structural limitations, and therefore is capable of performing the intended use." Final Act. 11–12; *see also* Ans. 7 ("there is very little which can structurally distinguish the device shown in Appellant[s'] Figure 5A–D [] from what can clearly be seen in Hastings '590 Figures 11G–H.").

Appellants assert that curved tines of the embodiment of Figs. 11E–K that follow a circular path are not the same or substantially the same as the claimed tines that bend back toward the implantable medical device into a hooked position, so the Examiner cannot rely on structural similarity to reasonably support that the forces required by the claims are necessarily present. Reply Br. 9. Rather than being curved so as to follow a circular path, Appellants assert that "[t]he tines of the present invention a[re] clearly disclosed [as] each having a straight section at their distal extremities that prevents them from following a circular path . . . . This structural difference is responsible for the pulling forces as required by the claims." *Id*. Appellants explain that:

the combination of curved and straight segments of the nitinol tines as disclosed in the present application means that they cannot simply assume their memorized configuration and therefore continue to exert radially inward force to pull the electrode inward toward tissue after deployment[.] This result occurs as a result of the super-elastic behavior of Nitinol. The difference in shape from the tines of Hastings produces the different mechanical characteristics, as required by the claims.

Appeal Br. 18 (emphasis omitted).

We agree with Appellants that the Examiner has not shown sufficient structural similarity between Hastings' adjustable tines 1110E and Appellants' tines, as disclosed and claimed, to justify concluding that Hastings' adjustable tines 1110E inherently perform the function of creating opposing radial forces to pull the implantable medical device toward patient tissue, as recited in independent claims 5 and 39.

The Examiner seeks to provide additional technical reasoning to support that Hastings' adjustable times 1110E can inherently perform the function of being "configured to create opposing radial forces when

deployed in unison such that the . . . tines pull the [IMD] towards the patient tissue when the . . . tines are deployed while the distal ends of the . . . tines are positioned adjacent to the patient tissue," as recited in independent claims 5 and 39. In particular, the Examiner finds that the "backward arcing motion [of the tines of the embodiment of Figures 11E–K] would create an outward, radial force and would pull the device toward tissue." Final Act. 12; see also id. at 4 ("This shape-memory directed expansion and curving of the tines [of Figures 11F–H] necessarily creates the opposing outward radial forces that would pull the IMD towards patient tissue as shown."); see also Ans. 9 (emphasis omitted) ("[t]he active fixation tines of the claims are configured to produce opposing radial forces simply because they are deployable from a spring-loaded position, bend back toward the implantable device when deployed, a[re] substantially equidistant from each other in a circular arrangement . . . , and made of a shape-memory alloy.").

Appellants disagree with the Examiner's additional technical reasoning and argue that the Examiner has not adequately demonstrated that the device of the embodiment of Figures 11E–K of Hastings would necessarily be configured to create opposing radial forces such that the tines pull the IMD toward the patient tissue when the tines are deployed while the distal ends of the tines are positioned adjacent the tissue. Reply Br. 6. Appellants assert that the drawings demonstrate that the tines "follow[] a circular path, [such that] the forces required by the claims are not necessarily present." *Id.* at 8 (emphasis omitted). *See also* Appeal Br. 17 (emphasis omitted) ("The tines in Figures 11E–K first extend distally outward from the electrode, not radially. This would tend to push the electrode away from the tissue, not pull it toward the tissue. Further, the radial outward forces that

later apply after the tines have penetrated are apparently balanced by one another and thus would not necessarily create a net distally directed force. The later forces associated with the tines as they continue proximally along their circular courses as illustrated in the drawings would not necessarily apply a force to pull [] the electrode distally toward the tissue because by this time, the tines would be braced distally against the tissue. Further movement along a circular path would not create a net force as required.").

We are persuaded by Appellants that the Examiner has not provided a sufficient basis to support the determination that the allegedly inherent characteristic of independent claims 5 and 39 *necessarily* flows from the teachings of Hastings. *See In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981).

As to the functional recitation in independent claim 7, the Examiner finds that Hastings' tines "are configured to provide a forward pressure to assure good electrode-tissue contact." Final Act 4 (citing Hastings, Figs. 11E–K, ¶ 18, 20, 70, 101, 133); see also Ans. 10 (Examiner appearing to rely on the purported structural similarity of Hastings' device to the claimed device in connection with claim 7). Appellants argue that in Hastings, "holding the electrode against the tissue is specifically a function of the associated fixation helix" and "[t]he curved tines keep the helix from being unscrewed." Appeal Br. 17. Appellants further argue that this manner of operation of Hastings is different than the electrode moving inward toward the tissue during deployment of the tines. *Id.* For the same reasons as described above in connection with independent claims 5 and 39, we agree with Appellants that the Examiner has not shown sufficient structural similarity between Hastings' adjustable tines 1110E and Appellants' tines,

as disclosed and claimed, to justify concluding that Hastings' adjustable tines 1110E inherently perform the function recited in independent claim 7.

As to the functional recitation in independent claim 12, the Examiner finds that Hastings' tines are "configured to facilitate releasing the IMD from the tissue without tearing the tissue by pulling the device away from the tissue." Final Act. 5 (citing Hastings, ¶¶ 84, 93, 110, 112, 113, 131); see also Ans. 10 (Examiner appearing to rely on the purported structural similarity of Hastings' device to the claimed device in connection with claim 12). The Examiner provides additional technical reasoning to support that Hastings' adjustable tines 1110E can inherently perform the function recited in independent claim 12. In particular, the Examiner finds that Hastings discloses that "the tines are retracted and the device repositionable within the tissue, which one of skill in the art would appreciate would be accomplished without damage to tissue due to retraction of the tines." Id. at 13. The Examiner also finds that Hastings discloses a pull force of 0.3 lbs, 0.5 lbs., or 1.0 lbs (id. (citing Hastings,  $\P$  112)), which is within the range of 1–5 N (or 0.22–1.1 lbs.) that Appellants have disclosed as being facilitative of removing the device without tearing patient tissue (id. (citing Spec. ¶ 76). See also Ans. 10 (making similar findings).

Appellants argue that in Hastings "[a]voiding tearing in conjunction with removal by pulling is not even stated to be possible," and instead "unscrewing the device after retraction of the tines is specified as the proper mechanism for removal." Appeal Br. 24. Appellants assert that "pulling the helix out will tear tissue, even if the total force required is quite small." *Id.* at 26. Appellants note that it is the entire assembly that is configured to facilitate releasing the IMD from tissue without tearing the tissue by pulling

the IMD, not just the tines. *Id.* Thus, Appellants argue that the Examiner cannot properly consider the device of Hastings without the helix. *Id.* at 27.

For the same reasons as described above in connection with independent claims 5 and 39, we agree with Appellants that the Examiner has not shown sufficient structural similarity between Hastings' adjustable tines 1110E and Appellants' tines, as disclosed and claimed, to justify concluding that Hastings' adjustable tines 1110E inherently perform the function recited in independent claim 12. Moreover, we are persuaded by Appellants that the Examiner has not provided sufficient technical reasoning to support a determination that the allegedly inherent characteristic of independent claim 12 *necessarily* flows from the teachings of Hastings.

As to the functional recitation in independent claims 19 and 20, the Examiner finds that deployment of the tines in Hastings would cause the "tines to pull the implantable medical device out of the lumen via the aperture." Final Act. 4 (citing Hastings, ¶¶ 99, 106, 119). Appellants argue that the tines in the embodiment of Figures 11E–K are "never described or shown as pulling the device out of the lumen of the catheter" and "[t]here is no inherent reason why they would necessarily perform this function." Appeal Br. 22. Appellants explain that the push rod pushes the device out of the catheter, and the tines are only advanced once the device is out of the catheter and inserted in the tissue. *Id.* at 22–23.

For the same reasons as described above in connection with independent claims 5 and 39, we agree with Appellants that the Examiner has not shown sufficient structural similarity between Hastings' adjustable tines 1110E and Appellants' tines, as disclosed and claimed, to justify concluding that Hastings' adjustable tines 1110E inherently perform the

function recited in independent claims 19 and 20. Moreover, we are persuaded by Appellants that the Examiner has failed to provide sufficient technical reasoning to support a determination that the allegedly inherent characteristic of independent claims 19 and 20 *necessarily* flows from the teachings of Hastings.

As to the embodiment of Figures 11V–W of Hastings alternatively relied on by the Examiner, the Examiner considers the analysis in connection with the embodiment of Figures 11E–K "to already address and support the maintained rejection based on the embodiment of Figures 11V–W." Ans. 10–11. Accordingly, we determine that the Examiner's position in connection with the embodiment of Figures 11V–W suffers from the same deficiencies as the Examiner's position in connection with the embodiment of Figures 11E–K.

For the foregoing reasons, we are persuaded that the Examiner erred in finding that Hastings discloses all of the limitations of independent claims 5, 17, 12, 19, 20, and 39, and we do not sustain the rejection of these claims under 35 U.S.C. § 102(b) as anticipated by Hastings. We also do not sustain the rejection of dependent claims 13, 14, and 21–30, which depend therefrom.

## **DECISION**

The Examiner's rejection of claims 5, 7, 12–14, 19–30 and 39 under 35 U.S.C. § 102(b) as anticipated by Hastings is reversed.

## <u>REVERSED</u>